

REMARKS

Claims 39-42, 44-56, and 58-62 are pending in this application. Claims 39, 41, 45, 46, 47, and 51 have been amended. Upon entry of this amendment claims 39-42, 44-56, and 58-62 will be pending. Applicant has further amended the pending claims to better recite the present invention. During an in-person interview on October 18th, 2007, the Examiner suggested reciting the first end and the second end are non-slidably coupled to the longitudinal element and that the Applicants provide support for this amendment and support or definition for the term “inelastic” added in a previous amendment as a modifier the flexible longitudinal element. The Examiner indicated that such amendment appeared to overcome the cited prior art references.

Claim Amendment Support

Regarding the term “substantially axially inelastic”, Applicant is using the common definition of inelastic as “lacking elasticity” where elasticity is defined in terms of physics as “the property of a substance that enables it to change its length, volume, or shape in direct response to a force effecting such a change and to recover its original form upon the removal of the force” *Random House Unabridged Dictionary*, © *Random House, Inc. 2006*. As such Applicant’s claimed longitudinal element is substantially unable to change its length or volume in direct response to a force while the longitudinal element is axially deflectable (flexible) and thus may change its shape in that manner. Support for this limitation is recited in the specification as filed, in particular **page 70, lines 16-21**, which recites

[I]t is understood that the present invention is not limited to a particular, predefined flexibility range. In one embodiment, in addition to having desired lateral flexibility characteristics, the rigidity of the rod 4 should be able to endure a vertical axial load applied to the patient's spinal column along a vertical axis of the spine in a uniform manner with respect to the rest of the patient's natural spine.

Further the specification states “the material used to manufacture the first and second tubes 5 and 30, respectively, may be any one or combination of the following exemplary metals: stainless steel, iron steel, titanium, and titanium alloy.” **Page 72, lines 10-12** where the tubes 5 and

30 may be the longitudinal element in an embodiment. Further, the longitudinal element may include wires. Applicant contends that the wires are also substantially axially inelastic as defined their application. The specification notes at **page 19, line 28** that a wire 32 may be pulled “to a desired tension”. Applicant contends that a wire could not be tensioned if it is axially elastic. Finally, the specification recites that the wire 32 is comprised of “a plurality of overlapping thin metallic yarns, such as steel yarns, titanium yarns, or titanium-alloy yarns.” **Page 72, lines 15-17**. Applicant respectfully contends that a rod or wire formed of the materials recited in the specification is substantially axially inelastic. Accordingly entry of the claim amendments reciting this term is respectfully requested.

Regarding the term “non-slidably” coupled as recited the claims relative to the coupling the longitudinal element to the first end or the second end, Applicant respectfully contends the specification provides support for this limitation. The specification at **Page 70, lines 25-27** states “[t]he rings or caps 9’ may be permanently affixed to the ends of the rod 4 using known methods such as pressing and/or welding the metals together.” Accordingly Applicant contends that in such a configuration the first end and the second end are not slidably couplable to the longitudinal element.

Prior Art Claim Rejections

The Examiner had rejected claims 39, 41-42, 46-48, and 52-54 under 35 USC 102(e) as being anticipated by US Publication No. 20040236327 to Paul et al. The Examiner had rejected claims 39, 42, 46, 51-52, 57, and 59-60 under 35 USC 102(e) as being anticipated by US Publication No. 20040143264 to McAfee. The Examiner had rejected claims 44-45, 49-51, and 55-62 under 35 USC 103(a) as being obvious over the US Publication No. 20040236327 to Paul et al. The Examiner had rejected claim 40 under 35 USC 103(a) as being obvious over the US Publication No. 20040143264 to McAfee in view of US Patent No. 6,530,934 to Jacobsen et al.

Claim 39 as currently amended:

A connection system for use in a bone fixation device, comprising:
a first bone coupling assembly adapted to be secured to a first vertebrae;
a rod comprising:
 a rigid first end portion including a surface received at least partially by and coupled to the first bone coupling assembly;
 a rigid second end portion;
 a longitudinal *flexible, substantially axially inelastic* member located between the first end portion and the second end portion, *non-slidably* coupled to the first end portion, and *non-slidably* coupled to the second end portion; and
 a *rigid* spacer located between the first and second ends portions and circumferentially disposed about the longitudinal flexible, substantially axially inelastic member;
a second bone coupling assembly coupled to the rod at a location other than the first end portion and adapted to be secured to a second vertebrae, the second vertebra adjacent to the first vertebrae,
 wherein the first and second ends portions *directly* limit motion of the rigid spacer along the longitudinal flexible, substantially axially inelastic member and the rigid spacer limits the minimum distance between the first vertebrae and the second vertebrae when the rod is coupled to the first vertebrae and the second, adjacent vertebrae via the first bone coupling assembly and the second bone coupling assembly.

Reiterating the arguments presented during the in-person interview on October 18th, 2007, Applicant notes that the Paul reference in figures 12 and 12a discloses an “encased spring concept” having rods 102 attached to an elastic middle element 110 via attachment means 108 and a cross sectional diagram of a tube 106 having a flange 104. In the Paul reference at paragraph 0092 states “[t]he tube 106 preferably has a diameter sufficient to allow movement of the rods 102 and attachment means 108 in response to the movement of the spring”. As amended claim 39 recites a flexible, *substantially axially inelastic* member. The Paul reference clearly discloses an axially elastic member (coupled to the rods), in particular a spring 110. Further, the Paul reference only discloses encasing the spring 110 and ends 102 with a tube 106 that has a diameter greater than the diameter of the rods 102. Accordingly, the rods 102 do not *directly limit* the motion of the spacer (tuber in Paul) as recited in claim 39 (as amended). Accordingly, Applicants respectfully contend that claim 39 is not obvious or anticipated by the Paul reference.

The McAfee reference in Figures 5 and 11 describes a system including several metal pedicle attachment sleeves that slide on a rod where there may be an polymer bumper between two

metal attachment sleeves. McAfee discloses in paragraph 0005 that the invention is a “novel vertebral anchor spinal rod sleeve system that allows a vertebra to *slide* cephalad or caudad along a spinal rod system”. McAfee does not disclose a connection system that includes a *flexible* member; McAfee only discloses a metal rod. Further McAfee does not disclose *flexible* member *non-slidably* coupled to a first end portion where the first end portion is coupled to a first bone coupling assembly. The metal attachment sleeves are slidably coupled to the McAfee rod. Further, the McAfee reference does not a rigid spacer; the McAfee reference only discloses a polymer bumper. McAfee also does not limit the distance between two vertebra given the metal sleeves are slidably coupled to a non-flexible rod. Accordingly, Applicants respectfully contend that claim 39 is not obvious or anticipated by the McAfee reference.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Please contact the undersigned Attorney to discuss any remaining issues or claim proposals.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-1119** referencing docket no. **559552000123**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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